

MEDICINE BOARD[653]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76 and chapters 148 and 272C, the Board of Medicine hereby gives Notice of Intended Action to amend Chapter 13, “Standards of Practice and Principles of Medical Ethics,” and Chapter 23, “Grounds for Discipline,” Iowa Administrative Code.

Proposed rule 653—13.8(148,272C) establishes the standards of practice for a physician or surgeon or osteopathic physician who serves as a medical director at a medical spa. Proposed subrules 23.1(43) and 23.1(44) establish as grounds for discipline improper delegation and supervision with regard to rule 653—13.8(148,272C).

The Board approved these amendments during a regularly scheduled meeting on June 11, 2010.

Any interested person may present written comments on these proposed amendments not later than 4:30 p.m. on July 20, 2010. Such written materials should be sent to Mark E. Bowden, Executive Director, Board of Medicine, 400 SW 8th Street, Suite C, Des Moines, Iowa 50309-4686; or E-mailed to Mark.Bowden@iowa.gov.

There will be a public hearing on July 20, 2010, at 11 a.m. in the Board office, at which time persons may present their views either orally or in writing. The Board of Medicine office is located at 400 SW 8th Street, Suite C, Des Moines, Iowa.

These amendments are intended to implement Iowa Code chapter 148.

The following amendments are proposed.

ITEM 1. Adopt the following new rule 653—13.8(148,272C):

653—13.8(148,272C) Standards of practice—medical directors at medical spas—delegation and supervision of medical aesthetic services performed by qualified licensed or certified nonphysician persons. This rule establishes standards of practice for physicians or surgeons or osteopathic physicians or surgeons who serve as a medical director at a medical spa.

13.8(1) Definitions. As used in this rule:

“*Delegate*” means to entrust or transfer the performance of a medical aesthetic service to qualified licensed or certified nonphysician persons.

“*Medical aesthetic service*” means the diagnosis, treatment, or correction of human conditions, ailments, diseases, injuries, or infirmities of the skin, hair, nails and mucous membranes by any means, methods, devices, or instruments including the use of a biological or synthetic material, chemical application, mechanical device, or displaced energy form of any kind if it alters or damages or is capable of altering or damaging living tissue below the superficial epidermal cells, with the exception of hair removal. Medical aesthetic service includes, but is not limited to, the following services: ablative laser therapy; vaporizing laser therapy; nonsuperficial light device therapy; injectables; tissue alteration services; nonsuperficial light-emitting diode therapy; nonsuperficial intense pulse light therapy; nonsuperficial radiofrequency therapy; nonsuperficial ultrasonic therapy; nonsuperficial exfoliation; nonsuperficial microdermabrasion; nonsuperficial dermaplane exfoliation; nonsuperficial lymphatic drainage; botox injections; collagen injections; and tattoo removal.

“*Medical director*” means a physician who assumes the role of, or holds oneself out as, medical director or a physician who serves as a medical advisor for a medical spa. The medical director is responsible for implementing policies and procedures to ensure quality patient care and for the delegation and supervision of medical aesthetic services to qualified licensed or certified nonphysician persons.

“Medical spa” means any entity, however organized, which is advertised, announced, established, or maintained for the purpose of providing medical aesthetic services. Medical spa shall not include a dermatology practice which is wholly owned and controlled by one or more Iowa-licensed physicians if at least one of the owners is actively practicing at each location.

“Qualified licensed or certified nonphysician person” means any person who is not licensed to practice medicine and surgery or osteopathic medicine and surgery but who is licensed or certified by another licensing board in Iowa and qualified to perform medical aesthetic services under the supervision of a qualified physician.

“Supervision” means the oversight of qualified licensed or certified nonphysician persons who perform medical aesthetic services delegated by a medical director.

13.8(2) Practice of medicine. The performance of medical aesthetic services is the practice of medicine. A medical aesthetic service shall only be performed by qualified licensed or certified nonphysician persons if the service has been delegated by the medical director who is responsible for supervision of the services performed. A medical director shall not delegate medical aesthetic services to nonphysician persons who are not appropriately licensed or certified in Iowa.

13.8(3) Medical director. A physician who serves as medical director at a medical spa shall:

- a. Hold an active unrestricted Iowa medical license to supervise each delegated medical aesthetic service;
- b. Possess the appropriate education, training, experience and competence to safely supervise each delegated medical aesthetic service;
- c. Retain responsibility for the supervision of each medical aesthetic service performed by licensed or certified nonphysician persons;
- d. Ensure that advertising activities do not include false, misleading, or deceptive representations; and
- e. Be clearly identified as the medical director in all advertising activities, Internet Web sites and signage related to the medical spa.

13.8(4) Delegated medical aesthetic service. When a medical director delegates a medical aesthetic service to qualified licensed or certified nonphysician persons, the service shall be:

- a. Within the medical director’s scope of practice and medical competence to supervise;
- b. Of the type that a reasonable and prudent physician would conclude is within the scope of sound medical judgment to delegate; and
- c. A routine and technical service, the performance of which does not require the skill of a licensed physician.

13.8(5) Supervision. A medical director who delegates performance of a medical aesthetic service to qualified licensed or certified nonphysician persons is responsible for providing appropriate supervision. The medical director shall:

- a. Ensure that all licensed or certified nonphysician persons are qualified and competent to safely perform each medical aesthetic service by personally assessing the person’s education, training, experience and ability;
- b. Ensure that a qualified licensed or certified nonphysician person does not perform any medical aesthetic services which are beyond the scope of that person’s license, certification or registration unless the person is supervised by a qualified supervising physician;
- c. Ensure that all qualified licensed or certified nonphysician persons receive direct, in-person, on-site supervision from the medical director at least four hours each week and that the regular supervision is documented;
- d. Provide on-site review of aesthetic services performed by qualified licensed or certified nonphysician persons each week and reviews at least 10 percent of patient charts for services performed by qualified licensed or certified nonphysician persons;
- e. Be physically located within 60 miles of the location where qualified licensed or certified nonphysician persons perform medical aesthetic services at all times;

f. Be available, in person or electronically, at all times, to consult with qualified licensed or certified nonphysician persons who perform medical aesthetic services, particularly in case of injury or an emergency;

g. Assess the legitimacy and safety of all equipment or other technologies being used by qualified licensed or certified nonphysician persons who perform medical aesthetic services;

h. Develop and implement protocols for responding to emergencies or other injuries suffered by persons receiving medical aesthetic services performed by qualified licensed or certified nonphysician persons;

i. Ensure that all qualified licensed or certified nonphysician persons maintain accurate and timely medical records for the medical aesthetic services they perform;

j. Ensure that each patient provides appropriate informed consent for medical aesthetic services performed by qualified licensed or certified nonphysician persons and that such informed consent is timely documented in the patient's medical record;

k. Ensure that each patient receiving medical aesthetic services performed by qualified licensed or certified nonphysician persons is informed of the identity of the medical director if requested; and

l. Ensure that the board receives written verification of the education and training of all qualified licensed or certified nonphysician persons who perform medical aesthetic services at a medical spa, within 14 days of a request by the board.

13.8(6) *Exceptions.* This rule is not intended to apply to physicians who serve as medical directors of licensed medical facilities, clinics or practices that provide medical aesthetic services as part of or incident to their other medical services.

13.8(7) *Physician assistants.* Nothing in these rules shall be interpreted to contradict or supersede the rules established in 645—Chapter 327.

ITEM 2. Adopt the following **new** subrules 23.1(43) and 23.1(44):

23.1(43) Violation of the standards of practice for medical directors who delegate and supervise medical aesthetic services performed by nonphysician persons at a medical spa as set out at rule 653—13.8(148,272C).

23.1(44) Failure to provide the board, within 14 days of a request by the board as set out at 653—paragraph 13.8(5)“l,” written verification of the education and training of all nonphysician persons who perform medical aesthetic services at a medical spa.